**SCULPTRA TREATMENT CONSENT**
**MANDALA AESTHETICS**

I give my consent to:
**Sculptra** is a sterile suspension of poly-l-lactic acid, which is a biocompatible synthetic polymer from the alpha-hydroxy acid family (fruit acids). Sculptra is designed to help correct skin depressions, such as creases, wrinkles, folds, scars, hollows, skin aging, and facial lipoatrophy (loss of fat).

I understand the practice of medicine is not an exact science and therefore no guarantee can be given as to the results of the treatment referred to in this document. I accept and understand that the goal of this treatment is an improvement, not perfection, and that there is no guarantee that the anticipated results will be achieved.

There are certain inherent and potential risks and side effects with any injectable procedure and such risks include but are not limited to:

- Post-treatment discomfort, swelling, redness, discoloration, and bruising
- Initial swelling will be noticeable for at least several hours and perhaps as long as several days
- Micronodules, which may be non-visible or visible, may be felt when touching the skin
- Micronodules typically last from 5 to 12 months and may spontaneously disappear. They usually do not require treatment, and usually do not elicit any symptoms
- Granulomas may occur in rare instances, and may be associated with redness, tenderness, skin discoloration, or textural alteration. These granulomas may or may not require further treatment
- Induration, or a feeling of fullness or thickness, can be felt in the injected areas. This is a normal response of the treated tissue to the process of inflammation and neocollagenesis (new collagen formation). Simply massaging the treated areas gently 3 to 5 times per day for 3 to 5 minutes, 5 days after the injection can help minimize induration.
- Asymmetry
- Scarring
- Cold sore eruption
- Allergic reaction or rarely anaphylaxis (facial swelling, rash, difficulty breathing, edema) requiring emergency treatment
- Post treatment infection or injection site abscess
- Skin hypertrophy and/or atrophy
- Injection inadvertently into blood vessels with result in tissue damage or necrosis (lack of blood flow causing considerable damage/death to tissue)
- Treatment requiring further injectable therapy

This is strictly a voluntary cosmetic procedure. Other options have been discussed, including the choice of no treatment. It has been explained to me that throughout the treatment the administration of ice and local or topical anesthesia may be necessary. I have been informed of the risks involved and I consent to the use of local and or topical anesthetics if required.

**SCULPTRA TREATMENT CONSENT CONTINUED**

1. I understand that I should not proceed with treatment if I am allergic to subcutaneous, absorbable suture material
2. I understand that I should make my provider aware of any autoimmune disorders such as lupus, rheumatoid arthritis, Hashimotos or other that may prohibit this treatment
3. I understand that Sculptra should NOT be performed if I have the following medical conditions: Scleroderma, Ehlers-Danlos Syndrome (EDS), keloid scar formation, an active flare of an autoimmune condition
4. I understand that the injection procedure reactions could be: bruising, swelling, discomfort and temporary redness to the treated areas
5. I understand that the risks of these injection procedure reactions are greater if I have been drinking any alcohol in the 48 hrs prior to treatment, taking any aspirin or NSAID (Advil, Motrin, Ibuprofen, Naproxen, Aleve, etc.), or taking large doses of Gingko Biloba or more than 400 IU of Vitamin E per day

   **Antiplatelet treatments such as aspirin or NSAIDs should be temporarily stopped for at least a week before treatment. Taking certain medications such as Aspirin, Advil, Ibuprofen, and other blood thinners may lead to more bruising**

6. I understand that the most common device related adverse effect is the delayed occurrence of subcutaneous papules, which were confined to the injection site and were typically palpable (could be felt), asymptomatic and non-visible
7. I understand that it takes several weeks to months to see the effects of this treatment, and the appropriate way to do this is to treat, wait and reassess in 6-8 weeks
8. I understand that several vials of Sculptra may be necessary to achieve the desired results
9. I understand that Sculptra should not be injected while you have an active skin infection or inflammation in the treatment area and should not be injected into the pink area of the lip
10. I understand the side effects may include injection site discomfort, redness, bruising, bleeding, itching and swelling. Other side effects may include small lumps under the skin that are sometimes noticeable when pressing on the treated area. Larger lumps, some with delayed onset with or without inflammation or skin discoloration. In clinical studies, the numbers of small and large lumps were low and most resolved without treatment
11. I understand Sculptra should not be performed if I am pregnant or nursing

I have been informed that it is important to know and share my personal history to establish knowledge of any possible allergies to medicines, any diseases, my current medications, previous aesthetic treatments, as well as the history of facial herpes simplex, keloids, or any other circumstances that can alter or interfere with the results of the treatment, or cause the treatment to be contraindicated.

Aspects of this treatment and the potential risk and complications have been fully explained to me, and I have had the opportunity to ask questions about the procedure including the limitations. All information has been given to me in clear and simple language. I confirm that I am satisfied with the information I have received and that I understand all the elements of the procedure including the risks.

I consent to the taking of photographs to monitor treatment effects, as desired or recommended by my provider.

I understand the potential risks and complications and have chosen to proceed with the treatment of **Sculptra** after careful consideration of the possibility of risks both known and unknown, complications, and limitations.

**I certify that I have read, and fully understand the above paragraphs and that I have had sufficient opportunity for discussion to have any questions answered.**

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| **Patient name:** | **Practitioner Name:** |
| **Signature:** | **Signature:** |
| **Date:** | **Date:** |